

**UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK**

Mitsubishi Chemical Corporation,  
Mitsubishi Tanabe Pharma Corporation,  
Encysive Pharmaceuticals Inc., Glaxo Group  
Limited, and SmithKline Beecham plc,

Plaintiffs,

V.

Barr Laboratories, Inc. and  
Pliva-Hrvatska d.o.o.

Defendants.

Civil Action No. 07 CV 11614

**Electronically Filed**

Hon. Judge Koeltl

**GLAXO GROUP LIMITED'S AND SMITHKLINE BEECHAM PLC'S  
MEMORANDUM OF LAW IN SUPPORT OF  
MOTION FOR LEAVE TO FILE A SECOND AMENDED COMPLAINT**

## I. INTRODUCTION

Pursuant to Rules 15 and 21 of the Federal Rules of Civil Procedure, plaintiffs Glaxo Group Limited and SmithKline Beecham plc (together “Plaintiffs”), request leave to file a Second Amended Complaint adding SmithKline Beecham Corp. d/b/a GlaxoSmithKline (“SKB Corp.”) as a party plaintiff.

Plaintiffs' proposed Second Amended Complaint adding SKB Corp. as a party plaintiff should be allowed because:

- First, the proposed amendment will not prejudice defendants Barr Laboratories, Inc. and PLIVA-Hrvatska d.o.o. (the “Defendants”) in any way. Defendants have not answered Plaintiffs’ First Amended Complaint and the Court has not issued a Scheduling Order. Further, the parties have not engaged in discovery. Granting the proposed amendment will not, therefore, result in any scheduling delay or wasted resources.
- Second, adding SKB Corp. as a plaintiff will not significantly increase Defendants’ burden. SKB Corp. is an exclusive licensee of the patent-in-suit, and the exclusive United States distributor of Argatroban Injection—a commercial embodiment of the patent-in-suit. As a result, SKB Corp. is a proper party to this lawsuit.

- Third, the proposed amendment is not futile. The well-pleaded allegations of the proposed Second Amended Complaint allege that SKB Corp. holds an exclusive license to practice the patent-in-suit in the United States; that SKB Corp. is the exclusive distributor of Argatroban Injection in the United States; and that Defendants' infringement of the patent-in-suit will irreparably harm SKB Corp. These allegations sufficiently allege that SKB Corp. is entitled to relief as a result of Defendants' patent infringement.

## **II. PROCEDURAL HISTORY**

On December 28, 2007, plaintiffs Mitsubishi Chemical Corporation ("MCC"), Mitsubishi Tanabe Pharma Corporation ("MTPC"), Encysive Pharmaceuticals Inc. ("Encysive"), SmithKline Beecham plc ("SKB plc") and SKB Corp. filed a Complaint against Barr Laboratories, Inc. ("Barr") for the infringement of United States Patent No. 5,214,052 ("the '052 Patent").

After Plaintiffs filed their initial complaint against Barr, and while Plaintiffs were preparing their First Amended Complaint to add Pliva as a defendant, counsel for SKB plc and SKB Corp. learned that Glaxo Group Limited ("GGL") was an exclusive licensee of the patent-in-suit and that SKB Corp., an originally named plaintiff, was a non-exclusive licensee. Thus, the First Amended Complaint (filed and served on February 21, 2008) added GGL as a plaintiff, dropped SKB Corp. as a plaintiff, and added Pliva as a defendant. Pursuant to a Stipulation and Order signed by the Court, Defendants' answer is due on or before March 12, 2008.

Subsequent to the filing of the First Amended Complaint, the license agreement between SKB Corp. and GGL was amended to provide, among other things, that SKB Corp. is exclusive licensee of the patent-in-suit. SKB Corp., therefore, is now a proper party. Plaintiffs' proposed Second Amended Complaint seeks only to add SKB Corp. as

a named plaintiff and to clarify that it is the entity that sells Argatroban Injection in the United States.<sup>1</sup>

Plaintiffs MCC, MTPC, and Encysive have assented to the instant motion. Counsel for Plaintiffs attempted to obtain Defendants' assent to this Motion, but Defendants refused and requested copies of any agreements granting rights in the patent-in-suit.

### **III. ARGUMENT**

#### **A. Federal Rules of Civil Procedure 15 and 21 Require That Leave To Amend Shall Be Freely Given.**

Motions to amend are governed generally by Rule 15(a) of the Federal Rules of Civil Procedure.<sup>2</sup> However, if the proposed amendment seeks to add a new party, then Rule 21 controls. Bridgeport Music, Inc. v. Universal Music Group, Inc., \_\_F.Supp.2d\_\_, 2008 WL 465072, \*4 -6 (S.D.N.Y. Feb. 15, 2008). Rule 21 provides that a party may be added to an action "at any time, on just terms." Fed. R. Civ. P. 21. In deciding whether to permit joinder of a new party under Rule 21, courts apply the "same standard of liberality afforded to motions to amend pleadings under Rule 15." Soler v. G & U, Inc., 86 F.R.D. 524, 528 (S.D.N.Y. 1980); State Farm Mut. Auto. Ins. Co. v. CPT Medical Servs., 246 F.R.D. 143, 146-47 (E.D.N.Y. 2007) ("no material difference exists between the standards articulated by Rules 15(a) and 21"). "Thus, joinder [of a new party under Rule 21] will be permitted absent undue delay, bad faith, prejudice, or futility." Schiller v. City of New York, Slip Op., No. 04 CIV 7922 (RJC) (JCF), 2008 WL 200021, \*3 (S.D.N.Y. Jan. 23, 2008). See also Foman v. Davis, 371 U.S. 178, 182 (1962)

<sup>1</sup> The proposed Second Amended Complaint and a blacklined version showing the proposed amendments are attached to the accompanying Notice of Motion and Motion for Leave to File a Second Amended Complaint ("Notice of Mot.") as Exhibits A and B.

<sup>2</sup> Rule 15(a) of the Federal Rules of Civil Procedure provides that parties may amend their pleadings "by leave of court," and that such leave "shall be freely given when justice so requires." Fed. R. Civ. P. 15(a); see Block v. First Blood Assocs., 988 F.2d 344, 350 (2d Cir. 1993); NAS Elecs., Inc. v. Transtech Elecs. PTE Ltd., 262 F.Supp.2d 134, 151 (S.D.N.Y. 2003) (Koeltl, J). This policy is to be applied liberally. See e.g., Nebraska v. Wyoming, 515 U.S. 1, 8 (1995).

(district court should evaluate several factors in determining whether justice requires granting leave to amend under Rule 15(a), including undue delay, undue prejudice to the opposing party, and futility of amendment).

**1. The Proposed Amendment Will Not Prejudice Defendants In Any Way**

“The rule in this Circuit [is] to allow a party to amend its pleadings in the absence of a showing by the nonmovant of prejudice or bad faith.” Block, 988 F.2d at 350. Defendants cannot meet their burden of demonstrating prejudice here because, quite simply, there is none. See Fariello v. Campbell, 860 F. Supp. 54, 70 (E.D.N.Y. 1994) (citing Panzella v. Skou, 471 F. Supp. 303, 305 (S.D.N.Y. 1979)) (party opposing the motion for leave to amend has the burden of establishing that an amendment would be prejudicial).

As an initial matter, Plaintiffs’ proposed amendment will not “significantly delay the resolution of th[is] dispute.” Monahan v. New York City Dep’t of Corrections, 214 F.3d 275, 283 (2d Cir. 2000) (setting forth factors court evaluates to determine if proposed amendment will cause prejudice). Defendants have not answered the First Amended Complaint, and their Answer is not due until March 12, 2008. Consequently, the parties have not discussed scheduling or case management, and the Court has not issued a Scheduling Order. Further, the parties have not engaged in discovery. Given the lack of a schedule in this matter and the preliminary stage of the dispute, the proposed amendment does not and cannot result in any significant scheduling delay.

In addition, Plaintiffs’ proposed amendment will not require Defendants “to expend significant additional resources to conduct discovery and prepare for trial.” Id. Plaintiffs’ proposed amendment is nearly identical to the First Amended Complaint. It

does not assert new or different claims for relief, and only seeks to add SKB Corp. as a party.<sup>3</sup> (See Notice of Mot., Exhibits A and B). Moreover, the addition of SKB Corp. will not alter the scope of the litigation. SKB Corp. presently holds an exclusive license under the patent-in-suit and is the exclusive United States distributor of Argatroban Injection, the commercial embodiment of the patent-in-suit. As a result, irrespective of Plaintiffs' proposed amendment, SKB Corp. will be involved in and the subject of discovery in this dispute. Therefore, the substance of Plaintiffs' proposed amendment does not inject any new issues into the case or impose any additional burden on Defendants in this litigation.

## **2. The Proposed Amendment Is Not Futile**

Plaintiffs' proposed amendment is not futile. A motion to amend may be denied as futile if the amendment would not withstand a Rule 12(b)(6) motion to dismiss. See Oneida Indian Nation of New York v. City of Sherill, 337 F.3d 139, 168 (2d Cir. 2003), rev'd on other grounds, 544 U.S. 197 (2005); Smith v. CPC Intern., Inc., 104 F.Supp.2d 272, 274 (S.D.N.Y. 2000). Thus, in evaluating the futility of a proposed amendment, the Court must accept all well-pleaded allegations in the complaint as true, and construe the complaint liberally in the light most favorable to the plaintiff. Bell Atl. Corp. v. Twombly, 127 S.Ct. 1955, 1965 (2007); Bernheim v. Litt, 79 F.3d 318, 321 (2d Cir. 1996).

Here, accepting all allegations as true, Plaintiffs' proposed Second Amended Complaint adequately sets forth "a short and plain statement of the claim showing that [SKB Corp.] is entitled to relief." Fed. R. Civ. P. 8(a)(2). In particular, the proposed amendment alleges that SKB Corp. (1) holds an exclusive license to the patent-in-suit; (2) is the exclusive distributor of

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<sup>3</sup> SKB Corp. was named as a plaintiff in the original complaint filed on December 27, 2008. Defendant Barr filed an Answer to that Complaint on February 11, 2008, and responded to allegations concerning, among other things, SKB Corp.

Argatroban Injection in the United States; and (3) will be substantially and irreparably harmed by Defendants' infringement of the patent-in-suit. (See Notice of Mot., Ex. A, at ¶¶ 14-16). These allegations "raise a right to relief above the speculative level." Twombly, 127 S.Ct. at 1965. See also Prima Tek II, L.L.C. v. A-Roo Co., 222 F.3d 1372, 1381 (Fed. Cir. 2000) (exclusive licensee has standing to sue for patent infringement). Accordingly, the proposed amendment would withstand a Rule 12(b)(6) motion and, therefore, should be allowed.

#### IV. CONCLUSION

For the foregoing reasons, Plaintiffs respectfully request that the Court grant their Motion for Leave to File a Second Amended Complaint, and that the Court provide such other and further relief as the Court deems appropriate.

Respectfully submitted,

Dated: February 29, 2008

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**CERTIFICATE OF SERVICE**

I, Robert J. Gunther, an attorney at law admitted to practice before this Court certify that on this 29th day of February, 2008, I caused to be served via ECF the plaintiffs' Memorandum of Law in Support of Motion for Leave to File a Second Amended Complaint on all counsel of record.

/s/ Robert J. Gunther, Jr.  
Robert J. Gunther, Esq.